

REMARKS/ARGUMENTS

Status of the Claims

Upon entry of the present amendment, claims 55, 58, 59, 63, 66 and 67 are amended, new claims 71-82 are added and claims 57, 61, 65 and 69 are canceled without disclaimer or prejudice to renewal.

Support for amending claims 55, 59, 63 and 67 is found, for example, on page 7, lines 19-26, in Figure 7, page 20, lines 5-17, and on page 30, lines 17-21.

Claims 58 and 66 are amended to become independent claims.

New claim 71 finds support, for example, on page 31, lines 4-9.

New claims 72-79 find support, for example, on page 7, line 19 through page 8, line 11 and in Figures 7 and 8.

New claim 80 finds support, for example, in claims 50 and 54 in the originally filed parent application.

New claim 81 finds support, for example, on page 1, lines 7-11 and on page 20, lines 6-11.

New claim 82 finds support, for example, on page 1, lines 7-11 and on page 22, lines 5-13.

Rejection under 35 U.S.C. § 112, second paragraph

The Examiner has rejected claims 55, 59 and 63 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for recitation of the phrase “for sufficient time and under conditions such that a blood type antigen is produced.”

To the extent that this rejection applies to the amended claims, Applicants respectfully traverse. The amended claims are directed to the production of alpha-1,2-fucosylated oligosaccharide blood type antigens. The specification teaches that skilled persons understood at the time of filing of the application that numerous methods could be employed in producing fucosylated oligosaccharides (of which alpha-1,2-fucosylated oligosaccharide blood type antigens are a subset) (*see*, page 20, lines 12-17). The specification further teaches that

standard enzymology techniques well-known in the art at the time of filing of the present application could be used to produce fucosylated oligosaccharides (*see, Id.*). The specification also teaches a range of suitable conditions for producing fucosylated oligosaccharides (*see, page 21, line 10 through page 22, line 4*). The skilled person would understand what constitutes conditions for producing alpha-1,2-fucosylated oligosaccharide blood type antigen based on knowledge in the art of standard enzymology techniques and exemplified suitable conditions taught in the specification, introducing modifications as appropriate (*see, page 21, line 10 through page 22, line 4; and page 46, lines 1-9*).

Because those of skill in the art would recognize suitable conditions for producing alpha-1,2-fucosylated oligosaccharide blood type antigens, the Examiner is respectfully requested to withdraw this rejection.

Rejection under 35 U.S.C. § 112, first paragraph, written description

The Examiner has rejected claims 55-57, 59-61, 63-65 and 67-69 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner alleges that the claims encompass four genera having many members with widely differing structural, chemical and physiochemical properties. *See, the present Official Acton at page 3.*

According to the MPEP, to satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail such that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. Possession may be shown in a variety of ways including description of an actual reduction to practice. Possession of a claimed invention may be demonstrated by description of the invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. MPEP § 2163(I).

To the extent that this rejection applies to the amended claims, Applicants respectfully traverse. As Applicants understand the Examiner's categorization of genera into polypeptides, polynucleotides, substrates and products; blood antigen substrates are related to blood antigen products, and alpha-1,2-fucosyltransferase polynucleotides are related to alpha-

1,2-fucosyltransferase polypeptides. The presently amended claims are directed to the production of alpha-1,2-fucosylated oligosaccharide blood type antigens from type 1 or type 2 oligosaccharide substrates, genera which share common structural, chemical and physiochemical properties. The presently amended claims further are directed to methods that use a *Helicobacter* alpha-1,2-fucosyltransferase polypeptide encoded by a polynucleotide that is amplified from *Helicobacter* genomic DNA by PCR using a first primer comprising 5'-GAACACTCACACGCGTCTT-3' and a second primer comprising 5'-TAGAATTAGACGCTCGCTAT-3'. The recited alpha-1,2-fucosyltransferase polypeptides and polynucleotides also encompass genera that share common structural, chemical and physiochemical properties. Applicants also describe and demonstrate how to produce oligosaccharide blood type antigens from type 1 or type 2 oligosaccharide substrates using the recited alpha-1,2-fucosyltransferases (*see, for example*, Figure 7, page 7, lines 19-26; page 20, line 5 through page 22, line 13; and page 46, lines 1-9).

In view of the foregoing, the Examiner is respectfully requested to withdraw this rejection.

Rejection under 35 U.S.C. § 112, first paragraph, enablement

The Examiner has rejected claims 55-57, 59-61, 63-65 and 67-69 under 35 U.S.C. § 112, first paragraph, as allegedly non-enabled.

In order to establish a *prima facie* case of lack of enablement, the Examiner has the burden to establish a reasonable basis to question the enablement provided for the claimed invention. *In re Wright*, 27 USPQ 1510, 1513 (Fed. Cir. 1993). As set forth in MPEP § 2164.01, "the test of enablement is not whether any experimentation is necessary, but whether... it is undue." Further, the "fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation" (citations omitted). Finally, claims reading on inoperative embodiments are enabled if the skilled artisan understands how to avoid inoperative embodiments. *See, e.g., In re Cook and Merigold*, 169 USPQ 299, 301 (C.C.P.A. 1971).

Here, the specification teaches and demonstrates to those of skill how to produce fucosylated oligosaccharides, which includes the subset of alpha-1,2-fucosylated oligosaccharide blood type antigens, in cell-containing and cell-free systems (*see*, page 20, line 5 through page 22, line 13; and page 46, lines 1-9). The specification teaches that standard enzymology methods known in the art can be utilized in producing fucosylated oligosaccharides (page 20, lines 12-17), teaches a range of suitable conditions for producing fucosylated oligosaccharides (*see*, page 21, line 10 through page 22, line 4), and that methods of using *Helicobacter* fucosyltransferases in particular were in the art and could be modified (page 46, lines 1-3). The specification further demonstrates that both type 1 and type 2 oligosaccharide substrates¹ could be fucosylated by the present alpha-1,2-fucosyltransferases, thereby producing both type 1 and type 2 oligosaccharide blood type antigens² (*see*, Figure 7 and page 7, lines 19-26). Based on the teachings in the specification and what was known by those of skill in the art at the time of filing of the present application, those of skill in the art could practice the presently claimed methods without undue experimentation.

In view of the foregoing, the Examiner is respectfully requested to withdraw the present rejection.

Rejection under 35 U.S.C. § 102(b), over U.S. Patent No. 5,595,900 (Lowe)

The Examiner has rejected claims 55-57, 59-61, 63-65 and 67-69 under 35 U.S.C. § 102(b) as allegedly anticipated by Lowe. To the extent that this rejection applies to the amended claims, Applicants respectfully traverse.

Proper anticipation requires that a reference teach each and every element of a rejected claim. MPEP § 2131.

Here, Lowe does not teach or suggest methods using any *Helicobacter* alpha-1,2-fucosyltransferase polypeptide or polynucleotide. Therefore, Lowe can not anticipate the

¹ Type 1 oligosaccharide substrates include, for example, H Type 1 precursor, and Lewis a; Type 2 oligosaccharide substrates include, for example, Lewis x.

² Type 1 oligosaccharide products include, for example, H Type 1, and Lewis b; Type 2 oligosaccharide products include, for example, Lewis y.

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presently claimed methods. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



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